510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041165

B. Purpose for Submission:
New menopause predictor device

C. Analyte:
Follicle Stimulating Hormone (FSH)

D. Type of Test:
Qualitative

E. Applicant:
ACON Laboratories, Inc.

F. Proprietary and Established Names:
FSH Menopause Predictor Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1300
2. Classification:
   Class I, meets the limitations of exemptions 862.9 (c) (9)
3. Product Code:
   CGJ
4. Panel:
   75 Chemistry

H. Intended Use:

1. Intended use(s):
   The FSH Menopause Predictor Test is a qualitative, one-step, midstream assay for the detection of Follicle Stimulating Hormone (FSH) in urine as a confirmation of body hormone changes related to the symptoms associated with the changes of menopause. The FHS Menopause Predictor Test is intended for use by the lay consumer.

2. Indication(s) for use:
   The FSH Menopause Predictor Test is a qualitative, one-step, midstream assay for the detection of Follicle Stimulating Hormone (FSH) in urine to be used as an aid in predicting menopause. The FSH Menopause Predictor Test is intended for over-the-counter use by the lay consumer.

3. Special condition for use statement(s):
   This is intended for over-the-counter (OTC) sales to lay consumers.

4. Special instrument Requirements:
   Not Applicable

I. Device Description:

The FSH Menopause Predictor Test is supplied with two wands that employ a combination of mouse monoclonal dye conjugate and goat polyclonal-solid phase antibodies on the test region and a package insert.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Instacheck® Menopause Predictor Test

2. Predicate K number(s):
   k023408

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	• Detection of FSH in urine	• Detection of FSH in urine
	• Qualitative test for use with urine.	• Qualitative test for use with urine.
Principle/Methodology	• Uses colorimetric visual interpretation	• Uses colorimetric visual interpretation
	• Require urine addition to the device	• Require urine addition to the device
Sensitivity	• 25 mIU/mL	• 25 mIU/mL
Differences		
Item	**Device**	**Predicate**
Principle/Methodology	Rapid chromatographic immunoassay using combination of mouse monoclonal dye conjugate and goat polyclonal solid phase antibodies.	Rapid chromatographic immunoassay using anti-FSH monoclonal antibody-colloidal gold conjugate and gold-labeled donkey antibodies.

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The device is a two-site sandwich immunochromatgraphic assay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Five batches of normal human urine demonstrated to be negative for FSH were spiked to levels of 0, 12.5, 25.0, 37.5 and 75.0 mIU/mL. Thirty-five consumers blindly tested each of the 5 batches. The results showed an excellent repeatability for all of the positive and negative blind urine samples.

Seventy-nine consumers were given 2 urine samples from women experiencing perimenopausal symptoms and/or irregular menstrual cycle. Seventy-five of the participants were able to correctly interpret their testing results as directed in the package insert.

b. Linearity/assay reportable range:

N/A

c. Traceability (controls, calibrators, or method):

WHO Urinary FHS 1st International Standard

d. Detection limit:

The sensitivity of the test is 25 mIU/mL. A panel of FSH was prepared by spiking human urine specimens with FSH to concentrations of 0, 12.5, 25.0, 37.5 and 75 mIU/mL. 35 devices per standard level were tested. Samples with concentrations of FSH equal to or greater than 25 mIU/mL were identified as positive for all samples. Samples lower than 25 mIU/mL were identified as negative for all samples.

e. Analytical specificity:

The specificity of ACON FSH Menopause Predictor test was tested with similar hormones and compounds found in normal human urine. Luteinizing hormones (1000 mIU/mL), human chorionic gonadotropin (100,000 mIU/mL) and thyroid stimulation hormone (1000 mIU/mL) were added to positive and negative urine and did not interfere with the results.

The specificity of ACON FSH Menopause Predictor test was tested with various OTC drugs, chemical and biological analytes. The analytes were added to a urine sample with negative FSH levels and a urine sample with 25 mIU/ML FSH level. None of the 22 substances tested interfered with the test results.

pH adjusted urine was tested in duplicate by adding FSH and did not interfere with the performance of the ACON FSH Menopause Predictor test.

f. Assay cut-off:

See Detection Limit above.

2. Comparison studies:
    a. *Method comparison with predicate device:*
    The ACON FSH Menopause Predictor test was compared to the InstaCheck® FSH Menopause test (K023408) using 70 women. 70 females, ages 40-58 tested their own urine at home using the ACON FSH Menopause Predictor test, followed by a trained laboratory technician. The technician tested each sample using the ACON FSH Menopause Predictor test and the InstaCheck® FSH Menopause. This process was repeated a week later.
    There was an accuracy of 94% between the ACON FSH Menopause Predictor test used by the consumer and the ACON FSH Menopause Predictor test used by a trained laboratory technician.
    There was a >99% agreement between the ACON FSH Menopause Predictor test and the InstaCheck® when conducted by a trained laboratory technician. There was a 94% accuracy between the consumer results and the professional InstaCheck® results. 69 tests were done with midstream test method and the others were conducted using the dip method.

    b. *Matrix comparison:*
    N/A

3. Clinical studies:
    a. *Clinical sensitivity:*
    N/A
    b. *Clinical specificity:*
    N/A
    c. *Other clinical supportive data (when a and b are not applicable):*
    N/A

4. Clinical cut-off:
    N/A

5. Expected values/Reference range:
    The expected values are based on literature and in previous sensitivity studies that demonstrated adequate performance at the cutoff of 25 mIU/mL.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.